K111775

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510(k) Summary
JBAIDS Influenza A & B Detection Kit

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Device Name: Trade Name:

JBAIDS Influenza A & B Detection Kit

Common Name:

Real-time PCR assay for detection of Influenza A and Influenza B

Classification Name:

Respiratory Viral Panel Multiplex Nucleic Acid Assay (CFR 866.3980)

Intended Use

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A & B Detection Kit is intended for use on the JBAIDS instruments, for the *in vitro* qualitative detection of Influenza A and Influenza B viral nucleic acids isolated and purified from nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens from human patients with signs and symptoms of respiratory infection. The JBAIDS Influenza A & B Detection Kit contains reverse transcriptase real-time polymerase chain reaction (rRT-PCR) assays that target the Matrix protein gene of Influenza A viruses, and the Non-structural protein gene of Influenza B viruses. This kit is not intended to detect Influenza C viruses.

Test results are to be used in conjunction with other clinical and epidemiological information. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for detection of influenza A were established when 2009 H1N1 Influenza, Influenza A H1N1, and Influenza A H3N2 were the predominant influenza A viruses in circulation. Due to low seasonal prevalence, performance characteristics for detection of seasonal Influenza A/H1 were established primarily with retrospective and surrogate clinical specimens. When other influenza A viruses are present, performance characteristics may vary.

All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by JBAIDS instructors or designees prior to use. Use of this device is limited to designated Department of Defense (DoD) laboratories equipped with the JBAIDS instruments.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a biosafety laboratory (BSL) 3+ facility is available to receive and culture specimens.

Device Description

The JBAIDS Influenza A & B Detection Kit is a rRT-PCR test kit, which, when used with the JBAIDS instrument and software, allows the qualitative in vitro detection of influenza A and B viral RNA. These two assays have been optimized as freeze-dried assays with primer and fluorescent-probe sets for the detection of influenza A and B viral RNA. In particular, the influenza A assay targets a region of the matrix gene specific to the influenza A virus genera, and the influenza B assay targets a region of the non-structural gene specific to the influenza B virus genera. The tests are performed using the previously FDA-cleared JBAIDS instrument and software. A human gene target assay (RNAseP target) will be used as an inhibition and extraction control.

Assay Principle

Before testing, NPS or NPW specimens are purified using Idaho Technology's 1-2-3™ Platinum Path Sample Purification Kit or the Roche MagNA Pure Compact Nucleic Acid Isolation Kit I. The resulting purified sample is added to Unknown reagent vials and a Sample Control reagent vial, along with reconstitution buffer. When viral RNA is present, a fragment of influenza A or B viral RNA is transcribed and amplified. The amplicon is detected by fluorescence using a specific hydrolysis probe. Each probe is labeled on one end with a fluorescent reporter moiety (6-carboxyfluorescein (6-FAM)) and elsewhere with a quencher moiety (carboxy tetramethylrhodamine (TAMRA)). When the probe is intact, the quencher absorbs the light emitted by the reporter moiety. During PCR, the probe hybridizes to the target sequence before the exonuclease activity of Taq polymerase hydrolyzes the probe, separating the fluorophore from the quencher and permitting detection of the fluorescent signal generated by the reporter. The fluorescent signal increases as additional templates are amplified and more probes are hydrolyzed.

JBAIDS Software analyzes the fluorescence amplification curves and reports results as positive, negative, or uncertain. A failure of the Positive or Negative Control will result in the entire run being called invalid. Failure of the Sample Control yields a result of "sample control failure" when the associated sample has a negative result for the target assay. Retesting is required to resolve uncertain, invalid or sample control failure results.

Substantial Equivalence

The JBAIDS Influenza A & B Detection System is substantially equivalent to other products in commercial distribution intended for similar use. The JBAIDS instrument has been previously cleared under K051713.

The JBAIDS Influenza A & B Detection Kit is substantially equivalent to the CDC Human Influenza Virus real-time RT-PCR Detection and Characterization Panel, which was cleared on September 30, 2008 under 510k# K080570.
The CDC rRT-PCR Flu Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis probes for the qualitative detection and differentiation of influenza viruses. The panel can be used to test upper respiratory tract specimens (including NPS, NS, TS, NA, NW, NPS/TS) and lower respiratory tract specimens (including BAL, BW, TA, sputum, and lung tissue) or virus culture.

Prior to testing, the samples are purified with one of four commercially available sample purification methods (see chart below). A PCR master mix is prepared by combining the appropriate quantities of primers and probes from the rRT-PCR Flu Panel with a commercially available reverse transcription enzyme master mix. The PCR master mix is aliquoted into a 96 well plate followed by addition of the purified samples and controls. The prepared plates are placed on an ABI 7500 Fast Dx Real-Time PCR instrument and thermocycled according to the cycling conditions described in the rRT-PCR Flu Panel product insert.

Each run on the ABI includes a no-template control (nuclease-free water), a seasonal influenza virus control (influenza A/H1, A/H3 and influenza B with cultured human cells), an A/H5 virus

control (noninfectious reassortant influenza A/H5 virus with cultured human cells) and a human specimen control (cultured human cells). The human specimen control is extracted with the test samples and is intended to ensure that the extraction process was properly performed. The no-template, seasonal influenza virus and A/H5 virus control templates are added to the PCR plate prior to thermocycling.

At the conclusion of the run, the operator is required to set a baseline for all assays included in the run. The operator is then required to interpret the test results for each sample based on the results of the control and the Ct values for each sample.

Table 1. Similarities Between the JBAIDS Influenza A & B Detection Kit and the CDC rRT-PCR Flu Panel

Element	JBAIDS Influenza A & B Detection Kit	CDC rRT-PCR Flu Panel (K080570)
Technology	Real-time PCR using hydrolysis probes	Same
Viruses Detected	Qualitative *in vitro* detection of influenza A and influenza B RNA	Same See below for differences
Specimen Types	Nasopharyngeal swabs	Same See below for differences
Extraction Methods	Roche MagNA Pure Compact Nucleic Acid Isolation Kit I	Same See below for differences

Table 2. Differences Between the JBAIDS Influenza A & B Detection Kit and the CDC rRT-PCR Flu Panel

Element	JBAIDS Influenza A & B Detection Kit	CDC rRT-PCR Flu Panel (K080570)
Viruses Detected	Does not subtype Influenza A viruses	Differentiation of Influenza A/H1, A/H3 and A/H5 (Asian lineage)
Specimen Types	Nasopharyngeal washes	Upper respiratory tract specimens (including NPS, NS, TS, NA, NW, NPS/TS) and lower respiratory tract specimens (including BAL, BW, TA, sputum, and lung tissue) and virus culture
Required Instrumentation	JBAIDS instrument	Applied Biosystems 7500 Fast Dx Real-time PCR instrument with SDS software v 1.4
Interpretation of Test Results	Automated analysis of test results and controls	User required to interpret test and control results
Enzyme Master Mix	Assays come in freeze-dried single use vials that include all components of master mix	Invitrogen SuperScript™ III Platinum® One-Step Quantitative RT-PCR Kits
Reagent Storage	Reagents are stored at room temperature	Reagents are stored at ≤ -15°C
Extraction Methods	IT *1-2-3*™ Platinum Path Sample Purification Kit Roche MagNA Pure Compact Nucleic Acid Isolation Kit I	QIAamp® Viral RNA Mini Kit, QIAGEN RNeasy® Mini Kit, or Roche MagNA Pure TNA Kit

Summary of Performance Data

Clinical Performance

The clinical performance of the JBAIDS Influenza A & B Detection Kit was evaluated during a prospective study at 5 geographically separated military clinical sites over the 2010-2011 influenza season (December 2010 to April 2011). Subjects with signs and/or symptoms of influenza-like illness were enrolled. Upon obtaining informed consent, NPS and NPW specimens were collected for JBAIDS and comparator testing. A total of 804 valid specimens were analyzed at the five study sites; 314 NPS and 490 NPW specimens. Table 3 provides a summary of demographic information for the 804 subjects that participated in the prospective study.

Table 3. Demographic Summary for the JBAIDS Influenza A & B Detection Kit Prospective Study

		Overall	Site 1	Site 2	Site 3	Site 4	Site 5
NPS		**314**	51	207	56	0	0
NPW		**490**	325	0	0	119	46
Total		**804**	376	207	56	119	46
Sex	Female	**410 (51%)**	192 (50.9%)	122 (58.9%)	23 (41.1%)	57 (47.9%)	16 (34.8%)
	Male	**394 (49%)**	185 (49.1%)	85 (41.1%)	33 (58.9%)	62 (52.1%)	30 (65.2%)
Age[a]	Avg.	**26.5**	23.4	24.5	30.3	23.1	31.0
	Median	**24.0**	24.0	18.0	27.5	17.0	27.0
	Min	**0.5**	0.5	0.5	2.0	0.5	18.0
	Max	**92.0**	92.0	69.0	81.0	68.0	62.0

[a] 0.5 was used for all ages under 1 year for these calculations.

Of the 804 prospective specimens, successful results were obtained for 97% (778/804) of these specimens on the first attempt (Site 1: 356/376 =95%; Site 2: 203/207 =98%; Site 3: 56/56 =100%; Site 4: 118/119 =99%; Site 5: 45/46 =98%). The remaining 3% (26/804) required retesting: "Invalid"(16/26), "Uncertain"(0/26), "SC Failure"(5/26), positive for both the Flu A and Flu B assays (2/26), or were re-extracted and retested due to user labeling error (3/26) (20 samples from Site 1; 4 samples from Site 2; 0 samples from Site 3; 1 sample from Site 4; and 1 sample from Site 5). All 26 samples were resolved upon a subsequent retest.

Nucleic acid from each specimen was isolated using either the IT *1-2-3* Platinum Path Sample Purification Kit (manual sample processing) or the Roche MagNA Pure Compact Nucleic Acid Isolation Kit I (automated sample processing) and tested with the JBAIDS Influenza A & B Detection Kit. The performance of the JBAIDS Influenza A & B Detection Kit was evaluated by comparing the JBAIDS test results with the comparator/reference method. The reference method was the CDC rRT-PCT Flu Panel influenza A and influenza B assays. Specimens collected at each study site were split into single use aliquots for testing with the JBAIDS Influenza A & B Detection Kit (performed at each site) and the CDC rRT-PCR Flu Panel influenza A and influenza B assays (performed at Idaho Technology) to determine Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA). PPA was calculated as 100% x (TP / (TP + FN)) and NPA was calculated as 100% x (TN / (TN + FP)). The exact binomial two-sided 95% confidence interval was calculated for both performance measures. The results are summarized in Table 1.

Table 1. JBAIDS Influenza A & B Detection Kit Prospective Clinical Performance Summary

Influenza Assay	Sample Type	Purification Kit	PPA		95% CI	NPA		95% CI
Flu A	NPW	Platinum Path	65/65	100.0%	94.5-100%	213/214	99.5%	97.4-100%
		MagNA Pure	39/39	100.0%	90.8-100%	170/172	98.8%	95.9-99.9%
		Combined	**104/104**	**100.0%**	**96.5-100%**	**383/386**	**99.2%**	**97.8-99.8%**
	NPS	Platinum Path	42/42	100.0%	91.6-100%	91/91	100.0%	96.0-100%
		MagNA Pure	20/20	100.0%	83.2-100%	160/161	99.4%	95.6-100%
		Combined	**62/62**	**100.0%**	**94.2-100%**	**251/252**	**99.6%**	**97.8-100%**
Flu B	NPW	Platinum Path	39/41	95.1%	83.5-99.4	237/238	99.6%	97.7-100%
		MagNA Pure	29/31	93.5%	78.6-99.2%	177/180	98.3%	95.2-99.7%
		Combined	**68/72**	**94.4%**	**86.4-98.5%**	**414/418**	**99.0%**	**97.6-99.7%**
	NPS	Platinum Path	18/19	94.7%	74.0-99.9%	114/114	100.0%	96.8-100%
		MagNA Pure	6/6	100.0%	54-100%	175/175	100.0%	97.9-100%
		Combined	**24/25**	**96.0%**	**79.7-99.9%**	**289/289**	**100.0%**	**98.7-100%**

Seasonal influenza A/H1 virus was not circulating during the 2010-2011 influenza season (http://www.cdc.gov/flu/) and was not detected during the prospective clinical study of the JBAIDS Influenza A & B Detection Kit. To supplement the results of the clinical study, an evaluation of preselected archived samples was performed. Due to the limited availability of archived specimens, the clinical performance was further supplemented with surrogate clinical contrived specimens.

Testing of Preselected Archived Specimens

Additional testing of pre-selected archived clinical NPS specimen was performed at two different clinical study sites to supplement the prospective clinical testing data. Because it is possible that the archived samples had been misidentified or had degraded during storage or previous handling, the presence or absence of Influenza A/H1 viral RNA was confirmed using "validation" PCR assays. The validation PCR assays were identical to

the comparator assays that were used for the prospective clinical evaluation study. A total of 51 NPS specimens were obtained and confirmed for testing: 30 known to be positive seasonal Influenza A/H1 specimens and 21 influenza-negative specimens. The specimens were split evenly for purification with the Platinum Path or MagNA Pure purification kits and then randomized such that the users performing the JBAIDS Influenza A & B Detection Kit testing were blinded as to the expected test result.

Table 5 presents the PPA and NPA for the archived clinical specimens. Data from both extraction kits are combined due to identical performance.

Table 2. Performance Summary of Seasonal Influenza A/H1 Archived Clinical Specimens

Influenza Assay	Sample Type	PPA	Percent	95% CI	NPA	Percent	95% CI
Flu A	NPS	30/30	100%	88.4-100%	21/21	100%	83.4-100%

Due to the absence of seasonal Influenza A/H1 virus in circulation during the 2010-2011 influenza seasonal (http://www.cdc.gov/flu/) and lack of availability of archived NPW specimens for seasonal Influenza A/H1, contrived clinical samples (residual influenza negative NPS and NPW samples spiked with a known concentration of seasonal Influenza A/H1 virus) were used as a surrogate to further evaluate the performance of the JBAIDS Influenza A & B Detection Kit.

Testing of Surrogate Clinical Specimens

A total of 136 individual influenza-negative clinical specimens (68 NPS samples and 68 NPW samples) were spiked at a range of concentrations, including near the system limit of detection (LoD), as well as un-spiked, then randomized, and sent to two different clinical trial study sites for testing. Of the 136 surrogate samples included in this study, a valid JBAIDS test result was obtained for 128 samples (62 NPW and 66 NPS). The remaining 8 samples with invalid results could not be retested due to insufficient sample volume, and were not included in the analysis.

Table 3 presents the PPA and NPA for the surrogate clinical specimens. Half of the samples were extracted using the Platinum Path purification kit and half using the MagNA pure kit.

Table 3. Performance Summary of Seasonal Influenza A/H1 Surrogate Clinical Specimens

Influenza Assay	Sample Type	PPA			NPA		
		TP/(TP+FN)	Percent	95% CI	TN/(TN+FP)	Percent	95% CI
Flu A	NPW	53/54	98.1%	90.1-100%	8/8	100.0%	63.1-100%
	NPS	59/59	100.0%	93.9-100%	7/7	100.0%	59.0-100%
Flu B	NPW	0/0	-	-	66/67[1]	98.5%	92.0-100%
	NPS	0/0	-		65/65	100.0%	94.5-100%

[1]Out of 67 valid sample results, one (1) false positive Flu B result was obtained, almost certainly due to switching of the Flu A and Flu B capillaries in the run setup.

Analyses of the clinical data set, preselected archived specimens, and surrogate clinical specimens demonstrate that the JBAIDS Influenza A & B Detection Kit is a sensitive and specific test system for the detection of influenza A and influenza B viruses.

Selected Analytic Studies

Limit of Detection

The analytical sensitivity or Limit of Detection (LoD) for each target assay (Flu A and Flu B) was determined using both NPS and NPW samples spiked with live, quantified virus strains. The LoD is defined as the lowest concentration at which the target is consistently detected (detection is ≥95% of samples tested). Independent specimens from independent donors were spiked with each live virus strain and 20 replicates were tested at the LoD concentration. The LoD levels for representative virus strains detected by the JBAIDS Influenza A & B Detection Kit are listed in Table 4.

Table 4. LoD Concentrations for Representative Virus Strains Detected by the JBAIDS Influenza A & B Detection Kit

Assay	Influenza Type	Strain	LoD (EID_{50}/mL)
Flu A	Influenza A H1N1	A/New Caledonia/20/1999	50
	Influenza A H3N2	A/New York/55/2004	5
	2009 Influenza A H1N1	A/New York/18/2009	50
Flu B	Influenza B	B/Ohio/1/ 2005	5
	Influenza B	B/Florida/ 7/2004	10

Inclusivity

The reactivity of the JBAIDS Influenza A & B Detection Kit assays was evaluated with an inclusivity panel consisting of 25 influenza A and 9 influenza B strains or isolates that represent the genetic, temporal, and geographic diversity of the influenza analytes. Each organism was tested in a simulated NPS sample matrix at or near the system LoD. Higher concentrations were tested if the analyte was not detected at the LoD. Each of the 34 influenza strains tested in this study was reactive with the appropriate JBAIDS influenza assays. Results from the inclusivity tested are presented in Table Error! **No text of specified style in document.** and Table 5. The concentration at which each strain was detected is indicated.

Table Error! No text of specified style in document.. **Results of Influenza A Inclusivity**

Influenza Type/Subtype	Strain	Lowest Concentration Detected
H2N2 (Avian)	A/chicken/Pennsylvania/298101-4/2004	0.5 $TCID_{50}$/mL
H3N8 (Avian)	A/MAL/ALB/16/87	50 $TCID_{50}$/mL
H4N8 (Avian)	A/chicken/Alabama/1975	5 EID_{50}/mL
H5N1 (Avian)	A/DK/PA/4560069-9/06	50 $TCID_{50}$/mL
H5N1 (Avian-Human Recombinant)	A/Vietnam/1203/2004(H5N1)-PR8	0.5 EID_{50}/mL
H6N2 (Avian)	A/Chicken/CA/32213-1/2000	0.5 EID_{50}/mL
H7N3 (Avian)	A/TY/UT/24721-10/95	500 $TCID_{50}$/mL
H9N2 (Avian)	A/Turkey/Wisconsin/1966	0.5 EID_{50}/mL
H3N8 (Canine)	A/canine/Florida/43/2004	5000 $TCID_{50}$/mL
H3N8 (Equine)	A/Equine/Ohio/01/2009	50 $TCID_{50}$/mL
H1N1 (Swine)	A/SW/GB/19582/92	50 $TCID_{50}$/mL
H1N1 (Swine)	A/swine/Wisconsin/125/1997	500 $TCID_{50}$/mL
H3N2 (Swine)	A/SW/IA/1/99	0.5 $TCID_{50}$/mL
H1N1 (Human of swine lineage)	A/Iowa/1/2006	500 $TCID_{50}$/mL
H1N1 (Human of swine lineage)	A/Maryland/12/1991	5000 $TCID_{50}$/mL
H7N2 (Human)	A/New York/107/2003	1×10^{-10} Dilution of Stock
Sesonal H1N1 (Human)	A/NWS/33	0.5 $TCID_{50}$/mL
	A/PR/8/34	5 $TCID_{50}$/mL
	A/1/Denver/1/57	0.5 $TCID_{50}$/mL
Seasonal H3N2 (Human)	A/Aichi/2/68	50 $TCID_{50}$/mL
	A/Hong Kong/8/68	5 $TCID_{50}$/mL
	A/Victoria/3/75	5 $TCID_{50}$/mL
2009 swine lineage H1N1 (Human)	A/England/195/2009	5 $TCID_{50}$/mL
	A/Mexico/4108/2009	500 EID_{50}/mL
	A/New York/18/2009	50 EID_{50}/mL

Table 5. Results of Influenza B Inclusivity

Strain	Lowest Concentration Detected
B/Lee/40	5 $TCID_{50}$/mL
B/Allen/45	50 $TCID_{50}$/mL
B/GL/1739/54	0.5 $TCID_{50}$/mL
B/Maryland/1/59	5 $TCID_{50}$/mL
B/Taiwan/2/62	0.5 $TCID_{50}$/mL
B/Hong Kong/5/72	0.5 $TCID_{50}$/mL
B/Malaysia/2506/04	50 $TCID_{50}$/mL
B/FL/04/06	50 $TCID_{50}$/mL
B/Brigit	0.5 $TCID_{50}$/mL

Exclusivity

The analytical specificity, or exclusivity, of the JBAIDS influenza assays was evaluated by testing simulated NPS samples spiked with high concentrations of influenza viruses (tens to thousands-fold higher than LoD). No cross-reactivity was observed when high

concentration of one influenza strain (e.g., influenza A) was tested with the alternate influenza assay (e.g., Flu B assay) at the concentrations listed in Table 6.

Table 6. Results of Testing for Cross-Reactivity with Influenza A and B Strains

JBAIDS Influenza Assay Tested	Type/Subtype (Host)	Strain	Concentration Tested
Flu A	Influenza B (Human)	B/Lee/40	7.36E+03 $TCID_{50}$/mL
		B/Allen/45	1.00E+05 $TCID_{50}$/mL
		B/GL/1739/54	7.36E+03 $TCID_{50}$/mL
		B/Maryland/1/59	7.36E+03 $TCID_{50}$/mL
		B/Taiwan/2/62	4.54E+04 $TCID_{50}$/mL
		B/Hong Kong/5/72	7.36E+03 $TCID_{50}$/mL
		B/Malaysia/2506/04	5.09E+03 $TCID_{50}$/mL
		B/FL/04/06	1.50E+04 $TCID_{50}$/mL
		B/Brigit	3.14E+04 $TCID_{50}$/mL
Flu B	H2N2 (Avian)	A/chicken/Pennsylvania/298101-4/2004	3.16E+07 $TCID_{50}$/mL
	H3N8 (Avian)	A/MAL/ALB/16/87	1.72E+03 $TCID_{50}$/mL
	H4N8 (Avian)	A/chicken/Alabama/1975	1.00E+08 EID_{50}/mL
	H5N1 (Avian-Human Recombinant)	A/Vietnam/1203/2004(H5N1)-PR8	3.16E+07 EID_{50}/mL
	H5N1 (Avian)	A/DK/PA/4560069-9/06	1.00E+05 $TCID_{50}$/mL
	H7N3 (Avian)	A/TY/UT/24721-10/95	3.06E+04 $TCID_{50}$/mL
	H6N2 (Avian)	A/Chicken/CA/32213-1/2000	1.26E+07 EID_{50}/mL
	H9N2 (Avian)	A/Turkey/Wisconsin/1966	5.60E+07 EID_{50}/mL
	H3N8 (Canine)	A/canine/Florida/43/2004	1.00E+05 $TCID_{50}$/mL
	H3N8 (Equine)	A/Equine/Ohio/01/2009	1.00E+05 $TCID_{50}$/mL
	H1N1 (Swine)	A/swine/Wisconsin/125/1997	1.00E+05 $TCID_{50}$/mL
	H1N1 (Swine)	A/SW/GB/19582/92	5.64E+03 $TCID_{50}$/mL
	H3N2 (Swine)	A/SW/IA/1/99	1.41E+03 $TCID_{50}$/mL
	H1N1 (Human of swine lineage)	A/Maryland/12/1991	1.00E+05 $TCID_{50}$/mL
	H1N1 (Human of swine lineage)	A/Iowa/1/2006	1.00E+05 $TCID_{50}$/mL
	H7N2 (Human)	A/New York/107/2003	30 µl of an unknown concentration into 1mL
	Seasonal H1N1 (Human)	A/Brisbane/59/07	1.00E+05 $TCID_{50}$/mL
		A1/FM/1/47	4.24E+03 $TCID_{50}$/mL
		A/PR/8/34	1.00E+05 $TCID_{50}$/mL
		A/NWS/33	4.24E+03 $TCID_{50}$/mL
		A/1/Denver/1/57	4.24E+03 $TCID_{50}$/mL
		A/Solomon Islands/3/2006	1.25E+04 $TCID_{50}$/mL
		A/Weiss/43	4.24E+03 $TCID_{50}$/mL
		A/Mal/302/54	1.25E+04 $TCID_{50}$/mL
	Seasonal H3N2 (Human)	A/Port Chalmers/1/73	5.10E+03 $TCID_{50}$/mL
		A/Victoria/3/75	4.24E+03 $TCID_{50}$/mL

JBAIDS Influenza Assay Tested	Type/Subtype (Host)	Strain	Concentration Tested
		A/Aichi/2/68	1.00E+05 $TCID_{50}$/mL
		A/Hong Kong/8/68	1.00E+05 $TCID_{50}$/mL
		A/Alice (VR-776)	4.24E+03 $TCID_{50}$/mL
		A/MRC-2 recomb (VR-777)	7.36E+03 $TCID_{50}$/mL
		A/Brisbane/10/07	7.36E+03 $TCID_{50}$/mL
	2009 swine lineage H1N1 (Human)	Swine NY/02/2009	1.25E+04 $TCID_{50}$/mL
		Swine NY/03/2009	7.36E+03 $TCID_{50}$/mL
		Swine NY/01/2009	3.78E+04 $TCID_{50}$/mL
		A/Mexico/4108/2009	1.00E+05 EID_{50}/mL
		A/California/8/2009	1.00E+05 $TCID_{50}$/mL
		A/California/04/2009	1.00E+05 $TCID_{50}$/mL
		A/Texas/48/2009	1.00E+05 $TCID_{50}$/mL
		A/Washington/29/2009	1.00E+05 $TCID_{50}$/mL
		A/South Carolina/18/2009	1.00E+05 $TCID_{50}$/mL
		A/England/195/2009	4.74E+04 $TCID_{50}$/mL
		A/North Carolina/39/2009	1.00E+05 $TCID_{50}$/mL

The non-influenza exclusivity panel consisted of 17 bacteria, 18 viruses, and 1 fungus, which were selected based on the relatedness to JBAIDS influenza analytes, clinical relevance (cause respiratory symptoms or represent nasopharyngeal flora), or high prevalence within the population (e.g. Herpes Simplex Virus). Simulated NPS samples were spiked with bacteria or fungi at a concentration of 10^6 CFU/mL or $TCID_{50}$/mL and viruses at a concentration between $10^3 - 10^5$ copies/mL or $TCID_{50}$/mL. The JBAIDS Influenza A and B assays did not cross-react with any of the organisms tested in the the exclusivity panel at the test concentrations listed in Table 7.

Table 7. Non-Influenza Exclusivity Panel

Virus	Concentration Tested	Bacteria/Fungi	Concentration Tested
Adenovirus	1.00E+05 $TCID_{50}$/mL	*Bordetella pertussis*	1.00E+06 CFU/mL
Bocavirus	4.20E+07 copies/mL	*Candida albicans*	1.00E+06 CFU/mL
Coronavirus 229E	7.35E+03 $TCID_{50}$/mL	*Corynebacterium diptheriae*	1.00E+06 CFU/mL
Coronavirus OC43	6.57E+04 $TCID_{50}$/mL	*Escherichia coli*	1.00E+06 CFU/mL
Coronavirus NL63	5.10E+03 $TCID_{50}$/mL	*Haemophilus influenza*	7.80E+04 CFU/mL
Coronavirus HKU1	1.00E+05 copies/mL	*Lactobacillus plantarum*	1.00E+06 CFU/mL
Cytomegalovirus (CMV)	1.50E+04 $TCID_{50}$/mL	*Legionella pneumophila*	1.00E+06 $TCID_{50}$/mL
Enterovirus	1.00E+05 $TCID_{50}$/mL	*Moraxella catarrhalis*	1.00E+06 CFU/mL
Epstein-Barr Virus (EBV)	1.00E+05 copies/mL	*Mycobacterium tuberculosis*	1.00E+06 CFU/mL
Human Metapneumovirus	7.35E+03 $TCID_{50}$/mL	*Mycoplasma pneumonia*	1.69E+05 $TCID_{50}$/mL
Human Rhinovirus	5.10E+03 $TCID_{50}$/mL	*Neisseria elongata*	1.00E+06 CFU/mL
Measles Virus (Rubeola)	1.00E+05 $TCID_{50}$/mL	*Neisseria meningitidis*	1.00E+06 CFU/mL
Mumps	4.53E+04 $TCID_{50}$/mL	*Pseudomonas aeruginosa*	1.00E+06 CFU/mL
Parainfluenza virus 1	1.25E+04 $TCID_{50}$/mL	*Staphylococcus aureus*	1.00E+06 CFU/mL
Parainfluenza virus 2	1.50E+04 $TCID_{50}$/mL	*Staphylococcus epidermidis*	1.00E+06 CFU/mL
Parainfluenza virus 3	1.00E+05 $TCID_{50}$/mL	*Streptococcus pneumonia*	1.00E+06 CFU/mL
Parainfluenza virus 4	1.00E+05 $TCID_{50}$/mL	*Streptococcus pyogenes*	1.00E+06 CFU/mL
Respiratory Syncytial Virus	1.25E+04 $TCID_{50}$/mL	*Streptococcus salivarius*	7.59E+05 CFU/mL

Reproducibility

A multicenter study was performed to determine overall system reproducibility. Reproducibility testing occurred at three test sites, utilizing four total panels. Panels of NPS and NPW samples, each, were spiked with a representative influenza A virus (A/New Caledonia/20/1999). Panels of simulated NPS and simulated NPW samples, each, were spiked with a representative influenza B virus (B/Ohio/1/2005). Samples in each panel consisted of three samples that were spiked below LoD (high negative, LoD/20), at a low concentration of virus (low positive, LoD), and at a medium concentration of virus (medium positive, 3×LoD) for a total of 9 samples per panel. Each panel was tested twice daily at each site for five days for a total of 30 results per sample and 90 results per spike level. The detection rate was ≥ 98% for samples containing influenza virus spiked at or above the LoD. As expected, samples spiked below LoD had variable results. Results are shown in Table 8 and Table 9.

Table 8. Summary of Reproducibility Testing for the Flu A Assay (Agreement with Expected Positive Results)

Sample Type	Virus Spike Level	IT 1-2-3 Platinum Path Sample Purification Kit Number Positive Samples/ Total Samples (% Positive Detection)				Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Number Positive Samples/ Total Samples (% Positive Detection)				Both Kits, All Sites	95% CI
		Site 1	Site 2	Site 3	Overall for All Sites	Site 1	Site 2	Site 3	Overall for All Sites		
NPS	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	89/90 (99%)	94.0-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**29/30 (97%)**	**30/30 (100%)**	**89/90 (99%)**	**179/180 (99%)**	**96.9-99.9**
	LoD/20	9/15 (60%)	11/15 (73%)	11/15 (73%)	31/45 (69%)	13/15 (87%)	14/15 (93%)	15/15 (100%)	42/45 (93%)	73/90 (81%)	71.5-88.6
	Detection all Levels	**39/45 (87%)**	**41/45 (91%)**	**41/45 (91%)**	**121/135 (90%)**	**43/45 (96%)**	**43/45 (96%)**	**45/45 (100%)**	**131/135 (97%)**	**252/270 (93%)**	**89.7-96.0**
NPW	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	89/90 (99%)	94.0-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**29/30 (97%)**	**30/30 (100%)**	**89/90 (99%)**	**179/180 (99%)**	**96.9-99.9**
	LoD/20	14/15 (93%)	11/15 (73%)	13/15 (87%)	38/45 (84%)	15/15 (100%)	13/15 (87%)	15/15 (100%)	43/45 (96%)	81/90 (90%)	81.9-95.3
	Detection all Levels	**44/45 (98%)**	**41/45 (91%)**	**43/45 (96%)**	**128/135 (95%)**	**45/45 (100%)**	**42/45 (93%)**	**45/45 (100%)**	**132/135 (98%)**	**260/270 (96%)**	**93.3-98.2**

Table 9. Summary of Reproducibility Testing for the Flu B Assay (Agreement with Expected Positive Results)

Sample Type	Virus Spike Level	IT 1-2-3 Platinum Path Sample Purification Kit Number Positive Samples/ Total Samples (% Positive Detection)				Roche MagNA Pure Compact Nucleic Acid Isolation Kit I Number Positive Samples/ Total Samples (% Positive Detection)				Both Kits, All Sites	95% CI
		Site 1	Site 2	Site 3	Overall for All Sites	Site 1	Site 2	Site 3	Overall for All Sites		
sNPS	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**180/180 (100%)**	**98.3-99.9**
	LoD/20	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	15/15 (100%)	14/15 (93%)	15/15 (100%)	44/45 (98%)	88/90 (98%)	92.2-99.7
	Detection All Levels	**45/45 (100%)**	**44/45 (98%)**	**45/45 (100%)**	**134/135 (99%)**	**45/45 (100%)**	**44/45 (98%)**	**45/45 (100%)**	**134/135 (99%)**	**268/270 (99%)**	**97.4-99.9**
sNPW	3×LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	LoD	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	90/90 (100%)	96.7-99.9
	Detection ≥ LoD	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**30/30 (100%)**	**90/90 (100%)**	**180/180 (100%)**	**98.3-99.9**
	LoD/20	14/15 (93%)	15/15[a] (100%)	12/15 (80%)	41/45 (91%)	15/15 (100%)	15/15 (100%)	15/15 (100%)	45/45 (100%)	86/90 (96%)	89.0-98.8
	Detection All Levels	**44/45 (98%)**	**45/45 (100%)**	**42/45 (93%)**	**131/135 (97%)**	**45/45 (100%)**	**45/45 (100%)**	**45/45 (100%)**	**135/135 (100%)**	**266/270 (99%)**	96.3-99.6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. Army Medical Materiel Development Activity
c/o Robert E. Miller, Ph.D., RAC
Director, Division of Regulated Activities and Compliance
1430 Veterans Drive
Fort Detrick, MD 21702-9232

SEP 13 2011

Re: k111775

Trade/Device Name:	JBAIDS Influenza A & B Kit
Regulation Number:	21 CFR §866.3980
Regulation Name:	Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class:	Class II
Product Codes:	OCC, OOI
Dated:	June 20, 2011
Received:	June 23, 2011

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k111775
Device Name: JBAIDS Influenza A & B Detection Kit

Indications for Use:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Influenza A & B Detection Kit is intended for use on the JBAIDS instruments, for the *in vitro* qualitative detection of Influenza A and Influenza B viral nucleic acids isolated and purified from nasopharyngeal swab (NPS) and nasopharyngeal wash (NPW) specimens from human patients with signs and symptoms of respiratory infection. The JBAIDS Influenza A & B Detection Kit contains reverse transcriptase real-time polymerase chain reaction (rRT-PCR) assays that target the Matrix protein gene of Influenza A viruses, and the Non-structural protein gene of Influenza B viruses. This kit is not intended to detect Influenza C viruses.

Test results are to be used in conjunction with other clinical and epidemiological information. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for detection of influenza A were established when 2009 H1N1 Influenza, Influenza A H1N1, and Influenza A H3N2 were the predominant influenza A viruses in circulation. Due to low seasonal prevalence, performance characteristics for detection of seasonal Influenza A/H1 were established primarily with retrospective and surrogate clinical specimens. When other influenza A viruses are present, performance characteristics may vary.

All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by JBAIDS instructors or designees prior to use. Use of this device is limited to designated Department of Defense (DoD) laboratories equipped with the JBAIDS instruments.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a biosafety laboratory (BSL) 3+ facility is available to receive and culture specimens.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111775